

**Remarks**

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

The Office Action is final. Upon entry of the present Amendment, Claims 1-16 are currently pending. Claims 13-16 have been withdrawn from further consideration as being directed to a non-elected invention. Claim 1 has been amended to further clarify and define the invention. Support for claim 1 can be found in paragraph [0044] on pages 15-16 of the present specification.

Entry of the Amendment is proper under 37 C.F.R. § 1.116, since the amendments and remarks are made in response to arguments raised in the final rejection, and place the application in condition for allowance.

Entry of the present Amendment is respectfully requested.

**Rejection Under 35 U.S.C § 112, First Paragraph**

Claims 1-12 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

In order to advance prosecution, Applicants have amended claim 1 to remove the term “vicinity” from the claim. Claim 1 has been amended to recite “...wherein the preservative is dispersed only in the coating composition which coats the biologically active substance.”

Support for claim 1 can be found in paragraph [0044] on pages 15-16 of the present specification. Specifically:

*(Preservative Agent) [0044] ...Particularly, when the preservative is blended and dispersed in a coating composition which coats the biologically active substance, such preservative can efficiently perform its preservative function without damaging the biologically active substance...It is also possible to improve a rumen bypass ratio by 10 to 50% when the preservative is dispersed in the coating composition so that attack by the rumen microorganisms may be inhibited. (Emphasis added).*

Applicants submit that based on the above, the preservative is only within the coating composition and is not included within the core part of the feed additive composition.

Applicants submit that this was acknowledged by the Examiner on pages 2-3 of the outstanding Office Action:

*Examiner notes the preservative is disclosed to be applied in a coating composition, but a coating composition is not a broad as being in the “vicinity” of the surface which may include within the core....(Emphasis added).*

Applicants contend that one skilled in the art, upon reading the specification as originally filed, would understand and conclude that Applicants had implicitly or inherently contemplated the added limitation within claim 1 and that it was in their possession at the time of filing the application.

Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejection Under 35 U.S.C § 112, Second Paragraph**

Claims 1-12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Applicants amended claim 1 to remove the term “vicinity” from the claim. Additionally, claim 1 has been amended to further clarify and define the invention, as indicated above.

Applicants submit that the claims, as indicated, particularly point out and distinctly claim the subject matter Applicants regard as the invention.

Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejection Under 35 U.S.C. § 103(a)**

Claims 1-12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kitamura *et al.*, U.S. Patent No. 5,676,966 (hereinafter “Kitamura”), in view of Bischoff *et al.*, U.S. Patent No. 4,770,876 (hereinafter “Bischoff”).

Applicants respectfully traverse the rejection.

The Examiner asserts that the present application is obvious in light of the above cited references, as indicated on pages 3-4 of the outstanding Office Action.

Based on the following, Applicants contend that the Examiner's position is not supportable, thereby making the presently claimed invention unobvious over Kitamura in view of Bischoff.

As previously indicated, MPEP § 2143 states that the Examiner must resolve the factors described in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which provides the controlling framework for an obviousness analysis, before utilizing the rationales that were established in *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

*Differences between the Invention and the Cited References*

Applicants provide the following information regarding the *Graham* factor of ascertaining the differences between the prior art and the claims that are at issue.

The presently claimed invention is directed to a feed additive composition for ruminants which has a biologically active substance coated with a coating composition. The coating composition comprises at least one protective material selected from the group consisting of a hardened animal fat, a hardened vegetable oil, a linear or branched, saturated or unsaturated aliphatic monocarboxylic acid having 12 to 22 carbon atoms, a fatty acid ester, and a wax group; lecithin; and at least one preservative selected from a propionic acid or a salt thereof, a sorbic acid or a salt thereof, a benzoic acid or a salt thereof, a dehydroacetic acid or a salt thereof, parahydroxybenzoic acid esters, an imazalil, a thiabendazole, an orthophenyl phenol, an orthophenyl phenol natrium, and a diphenyl. The preservative is dispersed only in the coating composition which coats the biologically active substance.

The Examiner asserts the preservative homogeneously mixed within the feed additive would still read on the previous claims.

First, Applicants have amended claim 1, which now clarifies that the preservative is dispersed only in a coating composition instead of within a biologically active substance. Further clarification of this aspect was made in amended claim 1 by adding “which coats the biologically active substance.”

Further, Applicants submit that with respect to the coating composition, the Examiner recognizes that the claim limitations complies partially in the feed additive composition, not the whole part of the feed additive composition, and that at least the coating composition is distinguished from the core, as indicated on pages 2-3 of the Office Action:

*Examiner notes the preservative is disclosed to be applied in a coating composition, but a coating composition is not a broad as being in the “vicinity” of the surface which may include within the core.... (Emphasis added).*

Accordingly, the presently claimed invention has a preservative dispersed in the coating composition, which is arranged outside the biologically active substance, which means that there is an uneven distribution within the feed additive composition.

On the contrary, none of the cited references disclose such a preservative that is partially located within the feed additive. In other words, Applicants submit that amended claim 1 emphasizes that the position of the preservative is limited, *i.e.*, the preservative is contained in the feed additive not uniformly, but partially. Particularly, the preservative is spread in the coating composition which is arranged outside the biologically active substance.

As previously indicated, this specific structure of the presently claimed invention achieves the effect as described in paragraph [0044] of the present specification:

*[0044] A preservative agent serves to inhibit a growth of mold, bacteria, etc. or exhibits an antibacterial action, and an antifungal agent etc. can be employed for such purposes...Particularly, when the preservative is blended and dispersed in a coating composition which coats the biologically active substance, such preservative can efficiently perform its preservative function without damaging the biologically active substance....(See paragraph [0044], pages 15-16, of the present specification; Emphasis added).*

In contrast, with regard to the Kitamura reference, the Examiner acknowledges on page 3 (last line) of the Office Action that “Kitamura does not teach the addition of propionic acid.” (Emphasis added). Inherently, Applicants submit that Kitamura does not disclose or imply a preservative at all.

Concerning the Bischoff reference, the Examiner has admitted in both Office Actions that “Bischoff et al does not teach the addition of the preservative in the coating.” (Emphasis added).

The Examiner also asserted that “it would have been obvious to the skilled artisan to include a preservative to in the coating and the core which is known to be compatible not only for the intended use of the composition, but also compatible with the components present in the composition.” (Emphasis added).

Applicants disagree with the Examiner’s obviousness rationale as it pertains to the presently claimed invention.

Applicants reiterate that the Bischoff reference merely discloses that preservatives may be compounded with the active compound, which is made into the formulation for livestock animals. Thus, the preservatives are just one of the admixtures for the mixed formulation.

Accordingly, Bischoff does not disclose or teach the preservatives wrapping the active compound itself, which fits the Examination’s view (*i.e.*, “Bischoff et al does not teach the addition of the preservative in the coating;” see the outstanding Office Action, page 4).

Likewise, Applicants submit that lecithin is regarded as an emulsifier which may be only mixed with the active compound for the formulation. Applicants note that Bischoff does not disclose lecithin for coating the active compound itself.

Applicants also submit that the Bischoff reference basically does not conceive of the idea of a coating composition for covering the active compound, which enables the substance to be

stably protected within the first stomach compartment (*i.e.*, the rumen) of ruminants and to be released in the abomasum and/or the subsequent digestive tract.

In view of the above, if the preservatives of Bischoff were to be combined with the feed additive composition of Kitamura (which does not disclose preservatives), Applicants submit that one of ordinary skill in the art would not be motivated to combine the references so as to integrate the feed additive composition with the preservatives directly or to limit the position of the preservatives uniquely.

Applicants also submit that the unlikely combination would lead the feed additive composition to include a preservative in both the coating and the core, as the Examiner has acknowledged.

Therefore, Applicants submit that the combination of the references is still missing the claimed matter that the preservative is dispersed only in the coating composition, being disposed heterogeneously in the feed additive composition. As a consequence, the combination of the cited references never attains the specific structure of the presently claimed invention.

Applicants submit that based on the differences discussed above, the Examiner has not resolved the *Graham* factor of ascertaining the differences between the prior art and the claims that are at issue, and therefore the rationale the Examiner provides for the rejection is improper.

Applicants note that although the above comments discuss the Kitamura and Bischoff references individually, this was only for discussing these references in terms of the *Graham* factor analysis. Applicants submit that taking the above *Graham* analysis in mind, the combination of Kitamura and Bischoff does not lead to the presently claimed invention.

In light of the above amended claims and remarks, Applicants submit that the assertions made by the Examiner regarding the Kitamura and Bischoff references are incorrect, thus failing to support the Examiner's position. Accordingly, based on the differences between the presently

claimed invention and the above references, the Kitamura and Bischoff references do not teach or suggest the presently claimed invention.

Since amended claim 1 is not obvious to one of ordinary skill in the art, claims 2-12, which ultimately depend from claim 1, are unobvious over the Kitamura and Bischoff references for the same reasoning discussed above.

Applicants respectfully request reconsideration and withdrawal of the rejection.

### **Conclusion**

Applicants respectfully submit that all of the rejections raised by the Examiner have been overcome, and that the present application now stands in condition for allowance.

Should there be any outstanding matters that need to be resolved, the Examiner is respectfully requested to contact Paul D. Pyla at the telephone number below, in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized to charge payment or credit any overpayment to Deposit Account No. 23-0975 for any additional fees required under 37 C.F.R. §§1.16 or 1.17.

Respectfully submitted,

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